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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,134	08/29/2005	Steven Jones	85084-402	3937

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
07/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,134	JONES ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,13-15,17,19-23,25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,13-15,17,19-23,25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Stacy Chen of Group Art Unit 1648.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2010 has been entered. Claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 are pending and under examination.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The citizenship of Steven Jones, Heinz Feldman and Ute Stroeher has been altered. None of the alterations have been initialed **and** dated, and one of the alterations has not been initialed. This error cannot be corrected by filing an application data sheet.

Specification

4. In the amendment to the specification on March 13, 2007, the first paragraph was amended to appropriately reference the PCT application and provisional application. However, in the amendment to the specification filed June 16, 2008, the first paragraph was amended to insert a repetitive sentence about the provisional application. Correction is required.

Claim Objections

5. Claim 15 is objected to because it lacks a period at the end of the sentence.

Response to Arguments

6. The rejection of claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 under 35 U.S.C. 103(a) as being unpatentable over Ito *et al.* (1999) in view of Kahn *et al.* (2001) and Vanderzanden *et al.* (1998) is withdrawn in view of Applicant's persuasive arguments and Points 3-6 of the declaration of Steven Jones and Ute Stroeher filed May 19, 2010.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 13-15, 17, 19-23, 25 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The embodiments of vaccines, or those containing immunogenic fragments of the G protein, methods of vaccination, and methods of obtaining passive vaccines for any VHF viruses are not enabled by the specification.

The breadth of the claims encompasses a vaccine and method of vaccinating with a live, infectious, replication-competent recombinant VSV pseudotyped with viral hemorrhagic fever glycoprotein. The recombinant VSV does not express any VSV glycoprotein on its surface, only the VHF glycoprotein or an immunogenic fragment thereof. A vaccine or immunization is able to induce an immune response in an individual such that upon challenge, the immune system is able to neutralize the pathogen and prevent disease. The claims broadly encompass protective vaccines and methods of protecting against Lassa, Marburg, Ebola, Crimean-Congo, Dengue, Nipah, Hendra, Machupo, Junin, Guanarito and Sabia virus. Also claimed is a method of preparing a pharmaceutical composition for passive immunization. The method comprises administering the above-described VSV pseudotyped particle to a subject, harvesting antibodies from the subject and mixing the antibodies with a suitable excipient or carrier. A passive vaccine is capable of neutralizing the invading pathogen such that disease is prevented.

The state of the art is that pseudotyped VSV is known to be a candidate vaccine vector. Kahn *et al*. (*J. Virology,* 2001, 75(22):11079-11087, "Kahn") discloses that foreign glycoproteins expressed in recombinant VSV can elicit specific and protective immunity in the mouse model (abstract). Kahn constructs recombinant VSV lacking the VSV G gene, contacted with cells expressing RSV F and G glycoproteins. Another construct is a recombinant VSV (lacking the G gene) that expresses RSV G and F, wherein the VSV G protein is supplied *in trans*. Kahn

reviews what others have done in the art, including attenuated recombinant VSV that express influenza hemagglutinin, measles virus hemagglutinin and HIV envelope protein (see page 11080, first column, first and second paragraphs). Takada *et al.* (*J. Virology*, 2003, 77(2):1069-1074, "Takada") discloses the construction of VSV containing Ebola virus glycoprotein-encoding gene instead of the VSV G gene. Takada also discloses the administration of antibodies induced after administration of the constructs, some of which protected mice from lethal Ebola virus infection (see abstract). In general, attempts at successful passive transfer of hyperimmune animal sera have been inconsistent (see page 1069, second column, first sentence).

Mahomadzadeh *et al.* (*Nature Reviews*, 2007, 7:556-567, "Mahomadzadeh") reviews the state of the art with regard to Ebola and Marburg viruses. Included in the review are VSV constructs wherein the filovirus glycoprotein replaces the VSV glycoprotein (see Table 1). Challenge experiments with the Ebola virus glycoprotein in various constructs in mice, guinea pigs and non-human primates has shown that the glycoprotein is critical for inducing immunity (see page 563). As for passive immunity, the results show promise but are not conclusive as to the ability of antibodies alone as protective immunotherapy in humans (see pages 563-564, bridging paragraph).

The guidance provided in the specification is limited to VSV-Ebola, Lassa and Marburg constructs. Applicant's challenge experiments are solely directed to these constructs, with challenge experiments in mice and guinea pigs. Applicant indicates that extrapolation of data from the guinea pig experiments would indicate that it will be protective in humans; further challenge experiments in non-human primates will be conducted (see page 16, first paragraph and third paragraph). Challenge experiments in acceptable animal models are required to lead

one of skill in the art to conclude that the constructs have potential as human vaccine candidates. (If Applicant have since performed these challenge experiments in non-human primates, Applicant is invited to submit that data in a declaration for further consideration as to the enablement of Ebola and Marburg vaccines.) As for passive immunity, Applicant indicates that it may be possible to use the constructs to generate serum for passive protection of humans against Ebola and other VHF agents (see page 16, second full paragraph). Further, with regard to the immunogenic fragment of a VFH glycoprotein being expressed from the VSV construct, the specification does not identify the relevant portions of the glycoproteins for each virus that are required to elicit the desired protective response.

In view of the breadth of the claims, the state of the art, the limited guidance in the specification and limited working examples, it would require undue experimentation to make and use the vaccines as claimed.

Conclusion

8. No claim is allowed. In view of the full enablement rejection set forth above, art rejections over the non-enabled subject matter are not addressed in this action but will be re-evaluated if the claims are deemed enabled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648